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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY/DOCKET NO.
08/530,112	07/10/95	MATSUMURA	06/02/99

HM22/0202

LYON AND LYON  
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LOS ANGELES CA 90071-2066

EXAMINER
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ART UNIT 632	PAPER NUMBER
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10  
02/02/99

DATE MAILED:

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No. <u>8/539,112</u>	Applicant(s) <u>Matsubara et al</u>	
Examiner <u>Campelli</u>	Group Art Unit <u>1632</u>	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 11/12/98
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-28 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 1, 3, 13, 21 is/are allowed.
- ☒ Claim(s) 2, 4-12, 14-20, 22-28 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☒ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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***Election/Restriction***

Applicant's election without traverse of SEQ ID Nos. 563, 709, 1017, 1219, 1320, 1449, 2058, 2965, 3084 and 4937 in Paper No. 9 is acknowledged.

***Claim Objections***

Claims 6, 9 and 12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can only cite multiple claims in the alternative. See MPEP § 608.01(n).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-12, 17-20 and 25-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the interim guidelines on written description published June 15, 1998 in the Federal Register at Volume 63, Number 114, pp. 32639-32645 (also available at [www.uspto.gov](http://www.uspto.gov)).

The claims are drawn to any DNA sequences complementary to a human mRNA (or a portion of a human mRNA) "containing" one of the ten elected sequences, "T" being read as "U." Each of the elected sequences is disclosed as a partial cDNA sequence consisting of, at most, the portion between the polyadenylation site and the most 3' Mbo I restriction site (specification, p. 8). Claims 7 and 10 clearly encompass cDNA sequences longer than those disclosed, including full-length cDNA clones. The claims also encompass DNA sequences complementary to unsequenced portions of the mRNA. Furthermore, because of the way in which "containing" is defined (specification, p. 10), the claims also encompass DNA molecules complementary to an infinite number of undisclosed sequences generated by inserting one or more nucleotides at one or more positions within the disclosed sequences.

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In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In this case, the only species whose complete structures are disclosed are DNA molecules complementary to the disclosed sequences, or portions thereof. This is not representative of the full scope of the claimed genus as described above. Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence). In this case, no other identifying characteristics of the claimed, but undisclosed, sequences are provided. Thus it is concluded that the written description requirement is not satisfied for all of the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-12, 17-20 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claims 7 and 10 are indefinite in their recitation of "containing." This term is defined in the specification (p. 10) to include sequences wherein any number of bases are inserted at any number of locations within the recited SEQ ID Nos. Thus the claim language fails to clearly set the metes and bounds of the claimed invention.

Claims 7 and 10 are vague and indefinite in their recitation of "3' region," which fails to clearly set the metes and bounds of the claimed invention.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 2, 5, 7, 8, 10, 11, 14, 16-20, 22 and 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by New England BioLabs. Catalog #1230 is a mixture of every possible DNA hexamer. Thus every possible hexamer portion of the claimed sequences (or their complements) was on sale more than one year prior to the effective filing date of the instant application.

Claims 2, 4-6, 10-12, 14-16, 19, 20, 22-24, 27 and 28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by any one of O'Banion et al., Louvion et al., Kawamura et al., Ploos van Amstel et al., Jenkins et al., Kaiser et al., Tsuzuki et al., Sor et al., Cabbage et al. or Adams et al.

Claims 2, 4-6, 10-12, 14-16, 19, 20, 22-24, 27 and 28 are drawn to nucleic acids that comprise, at a minimum, a portion of any of the elected polynucleotide sequences. Each of the references discloses a sub-sequence that is the same as or complementary to a region of at least 16 nucleotides in each of the ten elected SEQ ID NOs. The locations of these sub-sequences are shown in the table (EST Subsequences Taught in Prior Art) below. Both single stranded and double stranded DNAs are disclosed because the sequence of a single strand which is shown was obtained from a double stranded clone.

The Table below sets forth prior art that applies to the SEQ ID Nos. elected for examination and includes the position of identity in the claimed sequence and that of the prior art.

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## EST Subsequences Taught in Prior Art

SEQ ID NO	Reference	Location in Reference	Location in claimed SEQ ID NO	Location in Prior art SEQ
563	O'Banion et al.	Fig. 1	102-120	3327-3345
709	Louvion et al.	Fig. 2	147-130	626-643
1017	Kawamura et al.	Fig. 1	197-178	107-126
1219	Ploos van Amstel et al.	p. 7853, GenBank accession no. J02918	38-56	18-36
1320	Jenkins et al.	Fig. 2	99-117	567-585
1449	Kaiser et al.	GenBank accession no. X72408	21-38	83-100
2058	Tsuzuki et al.	Fig. 3	31-15	51-67
2965	Sor et al.	Fig. 2	155-172	1836-1853
3084	Cubbage et al.	Fig. 3	71-54	8994-9011
4937	Adams et al.	p. 153, GenBank accession no. Q39829	143-160	151-168

Since each of the references discloses a common sequence (or its complement) with one of the elected SEQ ID NOs, each of the references discloses a polynucleotide that is embraced by the claims.

**Conclusion**

Claims 1, 3, 13 and 21 are allowable. Claims 7-9, 17, 18, 25 and 26 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Campell, whose telephone number is 703-308-4205. The examiner can normally be reached on Monday-Thursday from 8:00 to 4:30 (Eastern time). The examiner can also be reached on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Stanton, can be reached on 703-308-2801. The FAX phone numbers for group 1600 are 703-308-4242 and 703-305-3014.

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An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read "Bruce R. Campell". The signature is written in a cursive, flowing style with a large initial "B".

**BRUCE R. CAMPELL  
PRIMARY EXAMINER  
GROUP 1600**